Attralus Therapeutic AT-02 Receives Orphan Drug Designation from the U.S. FDA for the Treatment of ATTR Amyloidosis

Naples, FL – November 12, 2024 – Attralus, Inc., a clinical stage biopharmaceutical company developing transformative medicines and diagnostics to improve the lives of patients with systemic amyloidosis, announced today that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation for AT-02 for the treatment of transthyretin-associated amyloidosis (ATTR), a rare, progressive, debilitating and often fatal condition.

AT-02, the company's lead pan-amyloid removal therapeutic candidate, is currently being evaluated in a three-part Phase 1 clinical trial and a Phase 2 open label extension trial in patients with systemic amyloidosis.

"We are pleased to have been granted orphan drug designation by the U.S. FDA for AT-02 in ATTR amyloidosis," said Gregory Bell, M.D., Chief Medical Officer at Attralus. "Current approved therapies for ATTR target precursor protein production, reducing the formation of new amyloid, but there is a significant unmet need for new therapies that can remove the existing toxic amyloid fibrils that cause organ damage and mortality."

The FDA Orphan Drug Designation program is granted to drugs and biologics intended for the safe and effective treatment, diagnosis or prevention of rare diseases or conditions affecting fewer than 200,000 people in the United States. Orphan Drug Designation provides benefits to sponsors designed to support the development of drugs and biologics for small patient populations with unmet medical needs. These benefits include tax credits for clinical costs, exemptions from certain FDA fees and potential seven years of marketing exclusivity.

Earlier this year, the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) issued positive opinions for AT-02 for ATTR and light chain (AL) amyloidosis which were adopted by the European Commission on August 21, 2024.

About AT-02, Pan-Amyloid Removal Therapeutic

AT-02 is the company's lead pan-amyloid removal (PAR) therapeutic candidate for systemic amyloidosis. AT-02 is a fusion protein of humanized immunoglobulin G1 (IgG1) with a pan amyloid-reactive peptide (p5R) genetically incorporated into the C-terminus of the light chain. The p5R peptide facilitates binding of the antibody to amyloid deposits of diverse types. The Fc region of the antibody stimulates the immune system to remove amyloid deposits that are bound by AT-02. AT-02 uses a similar pan-amyloid peptide to 124I-evuzamitide, the company's diagnostic agent, which has been shown in multiple clinical trials to selectively bind to amyloid deposits in the heart, liver, kidney, and other organs in multiple types of amyloidosis. As a result, the company expects AT-02 to bind specifically to amyloid in systemic amyloidosis patients. Preclinical data have shown the ability of AT-02 to bind to multiple amyloid types in major organs and induce macrophage mediated amyloid phagocytosis and amyloid removal. AT-02 is currently being evaluated in a 3-part Phase 1 trial and a Phase 2 open label extension trial in ATTR and AL amyloidosis patients.

About ATTR

Transthyretin amyloidosis (ATTR) is a severe, progressive, and fatal disease that is significantly underdiagnosed. ATTR is a systemic disease caused by accumulation of amyloid deposits in various parts of the body, including the heart, nerves, connective tissue, kidney and gastrointestinal tract. Patients with cardiac involvement, ATTR-CM, have a median survival of 3-5 years and the heart is the main determinant of mortality. There are two different forms of ATTR – hereditary ATTR (hATTR), which is caused by a TTR gene variant and wild-type ATTR (wtATTR), which occurs with aging. Both forms of ATTR affect the heart, and ATTR-CM affects 300,000-400,000 people in developed countries

About Attralus

Attralus is a clinical stage biopharmaceutical company focused on creating transformative medicines and diagnostics to improve the lives of patients with systemic amyloidosis. The company's proprietary pan-amyloid removal (PAR) therapeutics are designed to directly bind to and remove toxic amyloid in organs and tissues. By targeting the disease-causing pathology in systemic amyloidosis diseases, PAR therapeutics have the potential to treat and reverse disease in patients with all types and stages of systemic amyloidosis. Attralus was founded by scientific experts in the field of amyloidosis and the company is headquartered in Naples, FL.

Forward-Looking Statements

This press release contains forward-looking statements, including statements related to the efficacy, continued development, and potential of AT-01. Words such as "developing," "potential," "shown" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Attralus' current expectations. Forward-looking statements involve risks and uncertainties. Attralus' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. Attralus expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Attralus' expectations with regard thereto or any change in events, conditions, or circumstances on which any such statements are based.

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